REMARKS

The pending Office Action addresses and rejects claims 1-17, 19, 20, 23-26, 28-32, 34-44, 46, and 47. Applicants respectfully request reconsideration and allowance based on the remarks submitted herewith.

Rejections Pursuant to 35 U.S.C. § 103

Claims 1-17, 19-20, 23-26, 29, 34-44, 46 and 47 have been rejected under 35 U.S.C. 103(a) as anticipated by Schultz [US 6,256,5221] in view of Krauth [US 4,954,4351], in view of Vo-Dinh [US 5,864,397], and further in view of Mills [US 6,123,700].

Claim 1, as previously amended, claims a device for detecting the presence of an analyte in a sample. The claim requires a core comprising of a binding substrate with an analyte binding site, an analogue that binds in the binding site and which has a label with a first emission wavelength, a quenching dye, a reference having emission wavelength different from label, and an *analyte permeable membrane transparent to light of the wavelengths* used to excite label and reference, *wherein the device is seamless* and the binding substrate has molecular imprint of the analyte. None of the references either alone or in combination teach or even suggest such a seamless sensor device having a permeable membrane transparent to light. The remaining claims all depend from Claim 1.

The ability to construct seamless devices has many advantages, such as increased resistance to rupture due to mechanical stress, reduced risk of an immunological response, reduced irritation and inflammation post implantation, and ease of in vivo delivery.

As discussed in the Applicants' February 9, 2007 response, although Schultz illustrates the use of an implantable sensor capsule for measuring the concentration of certain bioanalytes in a patient, there is no mention of the sensor capsule being seamless in its construction. In fact, Schultz indicates that the sensor capsule may have two or more components joined mechanically by

screwed joints with O-rings, or preferably sealed by adhesion or heat. Alternatively, the sensor capsule may be composed of a small hollow cylindrical device having one integral end. The other end could be sealed via a suitable membrane held in place via a retainer ring.

Two of the other two references cited by the Examiner (Krauth et al., and Vo-Dinh et al.), disclose the use of multi-component external devices that can be used to detect concentration of an analyte.

One of ordinary skill in the art would not have any incentive to combine the teachings of Schultz (an implantable device) with that of Krauth and Vo-Dinh (an externally placed device). Even if such references were to be combined, they still would not teach a seamless device for detecting the presence of an analyte.

In addition, Claim 1 as currently presented, requires that the binding substrate have a molecular imprint of the analyte of interest. As the examiner correctly points out, Schultz teaches a binding substrate encompassed within a sensor capsule, but fails to teach that the binding substrate has a molecular imprint of the analyte.

As discussed in Applicants' June 27, 2006 response, Krauth teaches detection of an analyte through an enzyme immunoassay by indirect colorimetric detection. An incident light beam at a plurality of wavelengths is directed into a solution of the analyte. The solution is capable of attenuating, by absorption, the amount of light at the first wavelength scattered from said incident beam, as a function of increasing analyte concentration. A light signal from the solution at the first wavelength is detected, and light at a second wavelength spectrally removed from the first, and which is not substantially attenuated by increasing concentration of analyte is also detected. A ratio of signal intensity at the two wavelengths is calculated and compared with ratios of signal intensities obtained from samples having known concentration of said analyte, to determine the concentration of analyte in the sample.

Furthermore, and as discussed previously, Vo-Dinh teaches an external probe that includes a member made of optically transmissive material for detecting analyte via Surface-Enhanced Raman Scattering Spectroscopy when placed in contact with it. The end of the member is made of a microparticulate first layer overlaid with a metal layer for enhancing the Raman signals. An optional layer having a molecular imprint of the analyte of interest may be applied to the metal layer to concentrate analyte of interest.

Unlike the invention of Claim 1, neither Vo-Dinh nor Krauth contain an analyte permeable membrane encapsulating the core sensor elements and reference. Consequently, none of Schultz, Vo-Dinh, or Krauth either alone or in combination set forth all the limitations of claim 1, namely a device which is seamless and encapsulates the core sensor elements and reference and which is transparent to certain wavelengths of light.

The Examiner now asserts that Mills remedies these deficiencies by teaching "a sealed, implantable, encapsulation device (column 4, lines 10-15), and further teach a technique of forming the device into one permanent seamless bulk material (column 18, lines 26-43)." The Examiner argues that "one of ordinary skill in the art would have been motivated to make the invention of Schultz a seamless, unitary whole, as suggested by Mills et al."

Claim 1 as currently written requires, among other features, a device including "an analyte-permeable membrane that *encapsulates components (a) and (b)* and that is *transparent to light* of the wavelengths that excite the label and the reference, wherein the device is *seamless*." (Emphasis added).

It is clear from the disclosure of Mills that the alternate embodiment cited by the Examiner as teaching "forming of a device into a permanent seamless bulk material" is in fact a tubular membrane (21) having tubular fittings (32) which are "compressed together, by tweezers, pliers or the like, causing bonding surface (75) to contact abuttable surface (76)." (See Col. 18, lines 46-43). The contact between the bonding surface (75) and the abuttable surface (76) forms a seal, which is also a seam. In addition, the tubular fittings (32) are also joined to the tubular

membrane (21) by an overlapping joint, forming yet another seam. As shown in FIG. 18A and 18B, reproduced below, what is taught is not a seamless capsule, but simply a tube with sealed end fittings.

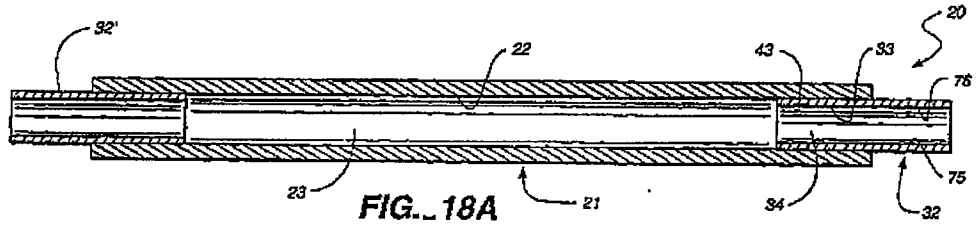

FIG._18A

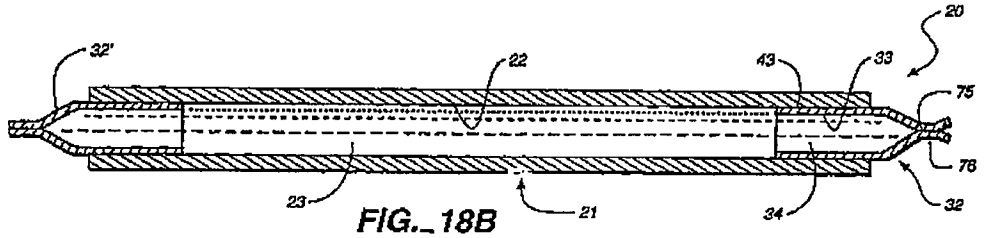

FIG._18B

Accordingly, Mills does not teach or even suggest forming an encapsulated device that is *seamless* as set forth in Claim 1.

In addition, Mills further discloses flushing the exposed surfaces of the device with a washing fluid that "causes the transparent tubing to turn milky-white in appearance. Such appearance results from the tubing precipitating out of solution into aggregates which diffract the visible light." (See Col. 18, lines 25-36). If one were to combine Mills with any of the previously cited references the result would be a seamed medical device with walls that are milky-white -- rendering the device no longer *transparent to light.* Consequently, rather than teaching a seamless encapsulation device, as asserted by the Examiner, the Mills reference effectively *teaches away* from the claimed transparent seamless capsule of the invention.

Third, one of ordinary skill in the art would not have been motivated to combine the teachings of Mills with any of the other cited references because the bonded seams of Mills do not provide any of the advantages of a seamless construction. Advantages of a seamless construction, such as increased resistance to rupture due to mechanical stress, reduced risk of an immunological response, reduced irritation and inflammation post implantation, and ease of in vivo delivery, would not be addressed by the multiple joints in the design disclosed by Mills. As such, there

would have been no advantage to combining Mills with any of the other cited references, and therefore no motivation to combine them.

For all of the reasons cited above, it is clear that none of the references suggest or disclose the device of this invention. Furthermore, there is no motivation to combine these references, and even if combined, they do not disclose or suggest the device of the present invention. Claim 1 is therefore patentable over the prior art.

Claims 2-47 depend from or otherwise incorporate all the limitations of Claim 1. As such they are patentable for at least the same reasons as Claim 1.

Conclusion

In view of the foregoing remarks, it is respectfully submitted that the application is in condition for allowance and Applicants earnestly solicit early examination on the merits and issuance of a Notice of Allowance. Should the Examiner believe that any additional information or amendment is necessary to place the application in condition for allowance, he is urged to contact the undersigned Attorney via telephone at 617-439-2746, or facsimile number 617-310-9746.

The Commissioner is hereby authorized to charge any required fees due in connection with this submission, including petition and extension of time fees, and to credit any overpayment to Deposit Account No. 141449 (Docket No. 106570-0002) (Lifescan Inc.).

Respectfully submitted,

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George A. Xixis
Reg. No. 38,664
Attorney for Applicants

NUTTER, McCLENNEN & FISH, LLP
World Trade Center West
155 Seaport Boulevard
Boston, MA 02110
Tel: (617) 439-2746
Fax: (617) 310-9746

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